



REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 12-25 remain under consideration. The Office raises rejections under 35 USC § 102(b) and 35 USC § 103(a).

Claims 12-17, 19, 20, 23, and 24 are rejected under 35 USC § 102(b) as being anticipated by Rault, et al. It is the position of the Office that Rault, et al. disclose a rapid release tablet composition comprising pirebedil, maize starch, and lactose. It is the further position of the Office that the composition of Example 2 of Rault, et al. contains 320 grams of pirebedil, 278 grams of lactose, and 80 grams of starch and that, based on these amounts, the composition contains 47% pirebedil and 52% lactose and starch. The Office therefore concludes that the composition of Example 2 anticipates the instantly claimed compositions.

Rault, et al. disclose a **bioadhesive** pharmaceutical composition which provides for the controlled release of active principles. The composition disclosed in Rault, et al. is comprised of an active principle, a compound (A) comprising one or more copolymers, and a compound (B) comprising one or more of a list of compounds which includes starches. The composition may further comprise other excipients which may act as diluents, binders, or lubricants. The reference lists lactose as an example of a diluent. The reference goes on to disclose that the bioadhesive properties of the composition are provided mainly by compound (A) and that the prolonged release properties are provided by the combination of compound (A) and compound (B). The tablet disclosed in Example 2 at column 4 of Rault, et al. is comprised of an "inner phase" comprising a mixture of pirebedil, modified maize starch, and lactose which is combined with an "outer phase" comprising a mixture of a copolymer and modified maize starch.

The Applicants respectfully submit that Rault, et al. do not disclose a pharmaceutical composition comprised of "**granules** consisting of co-dried lactose and starch." Moreover, the composition disclosed in Rault, et al. **requires** the presence of both compound (A) and compound (B) in order to achieve the rapid-release

characteristics of the disclosed composition. Thus, the disclosed **bioadhesive** composition of Rault, et al. neither anticipates nor renders obvious the instantly claimed **orodispersible** composition. Reconsideration and withdrawal of the anticipation rejection is respectfully requested.

Claims 12 and 25 are rejected under 35 USC § 102(b) as being anticipated by Dumont, et al. It is the position of the Office that Dumont, et al. disclose a method of treating Parkinson's disease with tablets of piribedil, which tablets contain lactose and starch, and that, therefore, this reference anticipates the instant claims. The Applicants respectfully submit that Dumont, et al. do not disclose a piribedil tablet comprising "**granules** consisting of co-dried lactose and starch," and that, therefore, the disclosure of Dumont, et al. neither anticipates nor renders obvious the instantly claimed composition nor the instantly claimed method. Reconsideration and withdrawal of the anticipation is respectfully requested.

Claims 12-24 are rejected for obviousness under 35 USC § 103(a) based on Khankari, et al. It is the position of the Office that Khankari, et al. disclose a hard compressed, rapidly dissolving tablet for oral dosage, comprising particles containing active ingredients, a matrix including non-direct compression fillers and a wicking agent and that the reference discloses that the dosage form is suitable for a variety of pharmaceutical ingredients. The Office goes on to state that the reference discloses lactose as an example of the non-direct compression filler and starches and/or modified starches as examples of wicking agents. The Office concludes that it would have been obvious to one skilled in the art to add piribedil as the active ingredient to the dosage form disclosed by Khankari, et al.

The formulation disclosed by Khankari, et al. is comprised of an active ingredient and a matrix, which matrix is comprised of at least a non-direct compression filler and a lubricant. The formulation may further include a wicking agent as well as other excipients. The reference further discloses that the "rapidly dissolving" formulations contain a "relatively high lubricant content" compared to the prior art. Moreover, Khankari, et al. do not disclose a tablet in which one of the components is comprised of "**granules** consisting of co-dried lactose and starch". Thus, the

Khankari, et al. disclosure does not render the instantly claimed compositions obvious.

With this Response and Amendment, the Applicants provide a Declaration by Marc JULIEN, a scientist skilled in this particular art, which speaks to the 35 USC § 103(a) rejections. Specifically, the Declaration provides data which demonstrate that the superior orodispersible properties associated with the instantly claimed compositions are attributable to the component of the instant compositions which consists of "**granules** consisting of co-dried lactose and starch" (i.e., the STARLAC® component). Consequently, the Applicants respectfully submit that the cited references, none of which disclose such a component nor the superior orodispersibility associated therewith, do not render the instant claims obvious.

Finally, the Applicants provide a copy of the Form PTO-1449 which was submitted with the filing papers of the instant application. It is respectfully requested that the information listed on the Form PTO-1449 be expressly considered during the prosecution of this application and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

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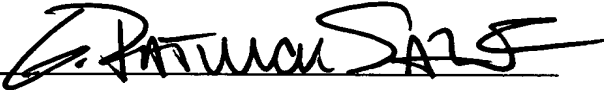
Accordingly, entry of the JULIEN Declaration, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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Enclosure: JULIEN Declaration; Copy of PTO-Form 1449; Fee for Three (3) Month
Extension; and Postal Card Receipt

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